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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1029; FRL-9368-2]

1,4-Dimethylnaphthalene; Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN) by expanding the current exemption to include all sprouting root and tuber vegetables (EPA Crop Group 01) and all bulb vegetables (EPA Crop Group 03). On behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., Technology Sciences Group, Inc. (TSG) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend the existing exemption from the requirement of a tolerance for 1,4-DMN. This regulation eliminates the need to establish a maximum permissible level for residues of 1,4-DMN under the FFDCA.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-1029, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0298; email address: *walsh.colin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-1029 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-1029, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7920) by TSG, Agent, 712 Fifth Street, Suite A, Davis, CA 95616, on behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., P.O. Box 860, Meridian, ID 83680. The petition requested that 40 CFR 180.1142 be amended by expanding the current exemption to include all sprouting root, tuber, and bulb crops, thus establishing an exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices. This notice referenced a summary of the petition prepared by the petitioner TSG, on behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., which is available in the docket via

http://www.regulations.gov. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... " Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider "available information concerning the cumulative effects of [a particular pesticide's] … residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

EPA established a tolerance exemption for 1,4-DMN in a Final Rule published in the **Federal Register** on February 8, 1995, (60 FR 7456-7457) (FRL-4932-4), which supported the plant growth regulator postharvest use on potatoes. The toxicological data submitted to support the previous tolerance exemption included the following: Acute (six-pack) toxicity, three mutagenicity studies, and a report of no hypersensitivity incidents for 1,4-DMN. The mutagenicity studies included an Ames test, an *in vitro* test for unscheduled DNA synthesis, and an *in vivo* micronucleus assay. All of the studies/information submitted to support the previous tolerance exemption indicated a lack of toxicity hazards for mammals, and EPA concluded that there is a reasonable certainty of no harm to humans, including infants and children, from the proposed food uses of 1,4-DMN. This amendment proposes to expand the tolerance exemption when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices. In support of this expansion of the tolerance exemption, new data have been generated by the petitioner and reviewed by EPA to address the developmental toxicity (OCSPP Guideline No. 870.3700) data requirement (the study was not submitted for the previous tolerance exemption). In addition, the petitioner submitted the following studies that were not required by EPA for this expansion of the tolerance exemption: *In*

vivo unscheduled DNA synthesis, *in vitro* skin absorption, dermal sensitization, one-generation reproductive toxicity, and a combined chronic toxicity/carcinogenicity (OCSPP Guideline Nos. 870.5550, 870.7600, 870.2600, 870.3800, and 870.4300, respectively). The developmental data are required when the use of the substance under widespread and commonly recognized practices may reasonably be expected to result in significant exposure to humans, specifically females of child-bearing age. The rest of the toxicological profile as stated in the February 8, 1995 issue of the **Federal Register**, and referenced herein, has not changed. The data submitted for the previous tolerance exemption include the acute toxicity (six-pack) studies, three mutagenicity studies, and a report of no hypersensitivity incidents for 1,4-DMN. A copy of the February 8, 1995 final rule document (60 FR 7456-7457) and risk assessments cited herein (Refs. 1 and 2) are located under docket ID number EPA-HQ-OPP-2011-1029.

As discussed in the **Federal Register** of February 8, 1995 (60 FR 7456) and risk assessments (Refs. 1 and 2), 1,4-DMN is naturally occurring and has a nontoxic mode of action. 1,4-DMN is found naturally occurring in potatoes (60 FR 7456) and detected in various other crops including cocoa, coffee, apples, corn, raisins, tomatoes, apricots, peaches, pear juice, eggplants, green peppers, star fruit, tea, radishes, oranges, cinnamon, poppies, and red beans (Ref. 1). When conditions are right for sprouting, the potato metabolizes 1,4-DMN to a low enough level so that sprouting can occur. 1,4-DMN is applied to postharvest sprouting root, tuber, and bulb stored crops at a level, generally 20 parts per million (ppm) up to 4 applications during a storage season, to continue to inhibit sprouting.

As stated previously in this Unit, new toxicity data have been submitted in support of the request by the petitioner to expand the current tolerance exemption to cover all sprouting root, tuber, and bulb crops. These data include: (1) a prenatal developmental toxicity study and (2) additional data not required by EPA, but used to further support the developmental data and this expansion of the tolerance exemption. All new data, coupled with the data submitted to support the previous tolerance exemption (60 FR 7456), confirm the minimal human health hazard effects, as reported in the original assessment of the tolerance exemption, associated with dietary exposures of 1,4-DMN and fully demonstrate the lack of mammalian toxicity. Summaries of the new toxicological data submitted in support of the expansion of the tolerance exemption follow.

A. Developmental Toxicity

A new developmental study (Master Record Identification (MRID) Number 48590905) was performed for 1,4-DMN to support the expansion of the tolerance exemption. 1,4-DMN was administered by oral gavage to female rabbits at the dose levels of 0, 25, 80, or 250 milligrams/per/day (mg/kg/day) (23 rabbits per test group) over gestation days 6 through 28. No treatment-related clinical signs were noted during the study, and gross necropsy findings were limited to those rabbits that underwent abortion (Ref. 1). The gross necropsy findings consisted of changes in the gastrointestinal tract (dilatation of stomach and/or intestines) and were likely related to the lack of eating prior to and during the abortion. Mean food consumption was significantly reduced in the 250 mg/kg/day treated doses shortly after treatment initiation (over gestation days 6 to 9 and 9 to 12). This reduction in food consumption was likely treatment-related. Corollary

reductions in mean body weight gain were observed in the 250 mg/kg/day treated group over gestation days 6 to 9. Alterations in uterus weight were not observed, nor were changes seen in maternal body weight or body weight gain when corrected for uterus weight. As such, the changes seen early on in gestational body weight gain were considered to be solely associated with maternal toxicity. Therefore, the lowest observed adverse effect level (LOAEL) for maternal toxicity of 1,4-DMN in rats is 250 mg/kg/day based on reduced food consumption and reduced body weight gain. The no observed adverse effect level (NOAEL) for maternal toxicity is 80 mg/kg/day based on no effects observed at this dose.

For developmental toxicity, no treatment-related differences in litter viability were detected at any dose level tested. The number of male, female, and total fetuses (sexes combined) were similar across the treatment and control groups and average fetal weights were unaffected. No structural alterations, including gross external, visceral, skeletal, and cephalic, were evident from the fetal examinations; as such, 1,4-DMN did not produce any frank malformations and was not teratogenic. Based on no effects observed for developmental toxicity at any doses tested, the NOAEL for developmental toxicity is greater than 250 mg/kg/day (highest dose tested). The LOAEL was not identified for developmental toxicity, suggesting that the test animals could have tolerated a higher dose.

Based on the developmental toxicity data submitted for this expansion to the tolerance exemption, which showed no adverse effects at the highest dose tested, 250 mg/kg/day, there are sufficient data and information to confirm that 1,4-DMN is not a developmental toxicant. Therefore, the consumption of food commodities that have been

treated with 1,4-DMN when used as a pesticide is safe and will not result in any harm to human health, specifically women of child-bearing age, from dietary exposure.

B. Additional Toxicity Data

Additional toxicity data for 1,4-DMN that were not required by EPA to support this expansion of the tolerance exemption were submitted by the petitioner. The additional data include the following: Unscheduled DNA synthesis (mutagenicity), *in vitro* skin absorption, dermal sensitization, one-generation reproductive toxicity, and a combined chronic toxicity/carcinogenicity study (OCSPP Guideline Nos. 870.5550, 870.7600, 870.2600, 870.3800, and 870.4300, respectively). Although the developmental data submitted were sufficient to support this expansion of the tolerance exemption, EPA has used this data, along with the required data submitted to support the previous tolerance exemption (60 FR 7456), to confirm that the consumption of food commodities that have been treated with 1,4-DMN when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

1. An *in vivo* unscheduled DNA synthesis in rats (MRID 48590902) showed no genotoxicity activity in rat livers when given a single dose of 1,4-DMN up to the limit dose of 1,000 mg/kg (Ref. 1). These results, combined with the lack of mutagenic and genotoxic effects observed in the bacterial reverse mutation (Ames) test, *in vitro* unscheduled DNA synthesis in mammalian cells, and *in vivo* mammalian erythrocyte micronucleus test submitted to support the previous tolerance exemption (60 FR 7456), confirm that 1,4-DMN is not a mutagen.

2. An *in vitro* precutaneous absorption test (MRID 48590903) in humans showed that the mean total dermal absorption of 1,4-DMN was 2.5% of the dose applied (Ref. 1).

Based on the relatively low absorption of 1,4-DMN and the data submitted to support the previous tolerance exemption (60 FR 7456), which included an acute dermal toxicity study that showed a low acute dermal toxicity (median lethal dose $(LD)_{50}$ > 2,000 mg/kg), 1,4-DMN is not considered a dermal toxicant.

3. A dermal sensitization test (MRID 48590904) utilizing the Local Lymph Node Assay (LLNA) method showed that 1,4-DMN is not a dermal sensitizer (Ref. 1). The dermal sensitization test utilizing the Buehler method submitted to support the previous tolerance exemption (60 FR 7456) also showed that 1,4-DMN is not a dermal sensitizer.

4. A one-generation reproductive toxicity study (MRID 48590906) was conducted on rats to assess systemic, developmental, and reproductive toxicity. 1,4-DMN was administered in the diet at the dose concentrations of 0, 500, 2,000, and 7,500 ppm with each dose group consisting of 24 males and 24 female rats. The results of the study showed that the NOAEL for systemic toxicity was 2,000 ppm (equivalent to 121 to 207 mg/kg/day in parental male and female rats and 184 to 213 mg/kg/day in F_1 males and females, respectively) and the LOAEL was 7,500 ppm based on a single histological change in the kidney of one, 7,500 ppm treated rat (Ref. 1). The NOAEL and LOAEL for developmental toxicity were also 2,000 ppm and 7,500 ppm, respectively, based on delayed vaginal patency and preputial separation in the 7,500 ppm group; although, the delay in development was considered secondary to body weight effects that were attributed to reduced food consumption. The NOAEL for reproductive toxicity was 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively) based on the lack of change in reproductive endpoints such as mating performance, fertility, fecundity, litter survival,

sperm morphology/vaginal cytology as well as the lack of histological change in the reproductive organs. The LOAEL was not identified for reproductive toxicity, suggesting that the test animals could have tolerated a higher dose.

Based on the reproductive toxicity data submitted for this expansion to the tolerance exemption, which showed no adverse reproductive effects at the highest dose tested, 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively), there are sufficient data and information to confirm that 1,4-DMN is not a reproductive toxicant, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

5. A combined chronic toxicity and carcinogenicity study (MRID 48590907) was conducted on rats (65 rats/sex/group for carcinogenicity and 20 rats/sex/group for chronic toxicity) to assess the chronic toxicity and carcinogenicity potential for 1,4-DMN. 1,4-DMN was administered in the diet of rats 7 days/week for a minimum of 52 weeks (chronic toxicity phase) or 104 weeks (carcinogenicity phase), at the dose concentrations of 0, 150, 500, and 3,750 ppm, equivalent to the dose concentrations of 0, 10, 33, and 250 mg/kg/day. For the chronic study, decreased food consumption with concurrent decreases in body weight and body weight gain were noted in the 250 mg/kg/day dose group. Minimal to moderate histologic test material-related effects in the kidney (proteinosis, papillary necrosis and karyomegaly) were noted in male rats at 250 mg/kg/day, while minimal to mild karyomegaly was noted in the kidney of female rats administered 1,4-DMN at dosages of 33 or 250 mg/kg/day. Based on the results of the

chronic toxicity study, the NOAEL for chronic toxicity was 33 mg/kg/day for males and 10 mg/kg/day for females. For the carcinogenicity study, no incidences of carcinogenicity were noted in rats in any of the dose concentrations after the 97 weeks and 104 weeks of treatment for female and male rats, respectively.

Based on the results of the carcinogenicity data submitted for this expansion to the tolerance exemption, which showed that there was no evidence of carcinogenicity at the highest dose tested, 3,750 ppm (equivalent to 250 mg/kg/day), there are sufficient data and information to confirm that 1,4-DMN is not a carcinogen, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary risks to humans are considered negligible based on the lack of significant dietary toxicological endpoints for 1,4-DMN, its non-toxic mode of action, and the fact that it is applied to postharvest root, tuber, and bulb crops at the relatively low application rate of 20 ppm up to four applications during the storage season. No significant acute, subchronic, mutagenic, developmental, chronic, or carcinogenicity dietary toxicity hazards were identified in the studies submitted to support this expansion of the tolerance

exemption or the previous tolerance exemption (60 FR 7456). The submitted data and information for this expansion of the tolerance exemption show that any residues of 1,4-DMN found in or on the sprouting root, tuber, and bulb crops are far below any toxicological endpoints identified in this expansion of the tolerance exemption or in the previous tolerance exemption (60 FR 7456) and confirm 1,4-DMN's lack of dietary toxicity hazards for mammals (Ref. 2).

1. *Food*. The petitioner submitted a scientific literature summary of the natural occurrence of 1,4-DMN in food crops (MRID 48653101) to support the expansion of the tolerance exemption from postharvest use on potatoes only, which are found in EPA Crop Group 01, to include all other sprouting root and tuber vegetables in the same EPA Crop Group 01 and all bulb vegetables (EPA Crop Group 03). Bulb vegetables include garlic, leek, onion, rakkyo, and shallot. As stated in the summary, 1,4-DMN has been detected in various crops including cocoa, coffee, apples, corn, raisins, tomatoes, apricots, peaches, pear juice, eggplants, green peppers, star fruit, tea, radishes (EPA Crop Group 01), oranges, cinnamon, poppies, and red beans (Ref. 1). It is likely that 1,4-DMN occurs naturally in other crops not listed in the literature summary, including crops in EPA Crop Group 01 (besides the already listed potatoes and radishes), and bulb crops in EPA Crop Group 03. The literature summary also indicated that the isomers of dimethylnaphthalene were shown to be present in various crops; however, the research indicates that it is extremely difficult to measure the amounts of the natural occurrence due to the volatility of the dimethylnaphthalene isomers, and any amounts reported are most likely an underestimation of the actual amount naturally present in the crop. As stated in Unit III of this final rule, the previous tolerance exemption (60 FR 7456)

indicated that 1,4-DMN is found naturally occurring in potatoes. When conditions are right for sprouting, the potato metabolizes 1,4-DMN to a low enough level so that sprouting can occur. 1,4-DMN is applied to postharvest potatoes at a level, generally 20 ppm up to four applications during a storage season, to maintain 1,4-DMN at a sufficient concentration in the potato to continue to inhibit sprouting.

Based on the submitted data and information for this expansion of the tolerance exemption, any residues of 1,4-DMN found in or on the sprouting root, tuber, and bulb crops are far below any toxicological endpoints identified in this expansion of the tolerance exemption or in the previous tolerance exemption (60 FR 7456). These toxicological endpoints identified in Unit III of this final rule include: Maternal toxicity NOAEL of 80 mg/kg/day, developmental toxicity NOAEL greater than 250 mg/kg/day, reproductive toxicity NOAEL of 7,500 ppm (equivalent to 441 to 591 mg/kg/day in parental male and female rats and 776 to 839 mg/kg/day in F_1 males and females, respectively), and chronic toxicity NOAEL of 33 mg/kg/day (500 ppm) for males and 10 mg/kg/day (150 ppm) for females. The previous tolerance exemption showed an acute oral toxicity LD_{50} of 2,730 mg/kg/day. In addition, under the conditions of the respective studies, there were no signs of mutagenicity or carcinogenicity for 1,4-DMN. In summary, the toxicity data submitted for 1,4-DMN, the natural occurrence of the substance in the various crops listed in this section, the nontoxic mode of action, the volatility of the isomers of dimethylnaphthalene, and the fact that it is applied to postharvest root, tuber, and bulb crops at the relatively low application rate of 20 ppm up to four applications during the storage season, demonstrate a lack of aggregate dietary risk that is sufficient to support this expansion of the tolerance exemption.

2. *Drinking water exposure*. No new drinking water exposure is expected to result from the new food uses of 1,4-DMN. Exposure of humans to 1,4-DMN in drinking water is highly unlikely since the products are labeled for postharvest application to sprouting root, tuber, and bulb crops stored in indoor facilities and are not applied directly to crops in the field. The data and information demonstrate a lack of aggregate dietary risk via drinking water and is sufficient to support this expansion of the tolerance exemption.

B. Other Non-Occupational Exposure

No new non-occupational exposure is expected to result from the new food uses of 1,4-DMN. No health risks are expected from any non-occupational exposure to 1,4-DMN based on the data submitted for the previous tolerance exemption (60 FR 7456) and for this expansion of the tolerance exemption.

1. *Dermal exposure*. No new non-occupational dermal exposure is expected to result from the new food uses of 1,4-DMN resulting from this expansion of the tolerance exemption. Any new dermal exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

2. *Inhalation exposure*. No new non-occupational inhalation exposure is expected to result from the new food uses of 1,4-DMN resulting from this expansion of the tolerance exemption. Any new inhalation exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information

concerning the cumulative effects of [a particular pesticide's] … residues and other substances that have a common mechanism of toxicity."

EPA has not found 1,4-DMN to share a common mechanism of toxicity with any other substances, and 1,4-DMN does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,4-DMN does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Relevant data and information submitted for the previous tolerance exemption (60 FR 7456) and for this expansion of the tolerance exemption indicate that 1,4-DMN has negligible acute, subchronic, mutagenic, developmental, chronic, or carcinogenicity toxicity hazards. Moreover, 1,4-DMN has a nontoxic mode of action and naturally occurs in various crops as listed in Unit IV.A.1. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of 1,4-DMN. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on 1,4-DMN do not demonstrate significant toxic potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above, and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 1,4-DMN.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 1,4-DMN. Therefore, the existing exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to potatoes is amended by establishing the exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-DMN, when applied postharvest to sprouting root, tuber, and bulb crops in accordance with good agricultural practices.

IX. References

The following references used in this document and the previous Final Rule published in the **Federal Register** on February 8, 1995, (60 FR 7456) (FRL-4932-4) are in the OPP docket listed under docket ID EPA-HQ-OPP-2011-1029 and may be seen by accessing the www.regulations.gov website.

1. U.S. EPA. 2012. Memorandum from Gina M. Burnett to Colin Walsh. Science Review of Tolerance Petition 1F7920, Intended to Expand the Use of 1,4-Dimethylnaphthalene to Include Use on All Root and Tuber Vegetables (Crop Group 01) and Bulb Vegetables (Crop Group 03); Label Amendments for 67727-1, -3 and -4 Upon

Tolerance Amendment Approval. U.S. Environmental Protection Agency, Office of Pesticide Programs. March 16, 2012.

2. U.S. EPA. 2012. Memorandum from Russell S. Jones, Ph.D., to Colin Walsh. Science Review of Registrant's Response to Deficiencies in Tolerance Petition 1F7920, Intended to Expand the Use of 1,4-Dimethylnaphthalene to Include Use on All Root and Tuber Vegetables (Crop Group 01) and Bulb Vegetables (Crop Group 03); Label Amendments for 67727-1, -3 and -4 Upon Tolerance Amendment Approval. U.S. Environmental Protection Agency , Office of Pesticide Programs. June 21, 2012.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 2012.

Keith A. Mathews,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.1142 to read as follows:

§180.1142 1,4-Dimethylnaphthalene; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN), when applied postharvest to all sprouting root, tuber, and bulb crops in accordance with good agricultural practices.

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